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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,633	10/14/2003	Michael S. Kopreski	00-1312-L	5239

7590 04/28/2006

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,633	KOPRESKI, MICHAEL S.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, drawn to a method for detecting, diagnosing, evaluating or monitoring cancer or premalignant disease in a human (claims 1 and 2), a method for extracting an RNA species from a non-cellular fraction of a bodily fluid using a probe that hybridizes with said RNA species (claims 3 and 4), a method for selecting a human or animal for an epidermal growth factor receptor-directed therapy (claims 5-7), and a method for monitoring response in a human or animal to an epidermal growth factor receptor-directed therapy (claims 8-10), a method for selecting a human or animal for a her-2/neu-directed therapy (claims 11-13), and a method for monitoring response in a human or animal to a her-2/neu-directed therapy, a method for selecting a human or animal for a tyrosine kinase-directed therapy (claims 17-19), and a method for monitoring response in a human or animal to a tyrosine kinase-directed therapy (claims 20-22), classified in class 435, subclasses 6 and 91.2.

II. Claims 23 and 24, drawn to a kit, classified in class 536, subclass 24.3 or 24.33.

III. Claims 25 and 26, drawn to a kit, classified in class 536, subclass 24.3 or 24.33.

IV. Claims 27 and 28, drawn to a kit, classified in class 536, subclass 24.3 or 24.33.

2. The inventions are distinct, each from the other because of the following reasons:

Group I and Groups II to IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group II or III or IV as claimed can be used in a materially different process of using that product such as a hybridization method using a chip or array.

Groups II and III are distinct and independent inventions in that they are directed to different products. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as primers or probes specific for epidermal growth factor RNA or epidermal growth factor receptor RNA species of claim 23 is not required for Group III while the search required for Group III such as primers or probes specific for her-2/neu RNA species of claim 25 is not required for Group II.

Groups II and IV are distinct and independent inventions in that they are directed to different products. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as primers or probes specific for epidermal growth factor RNA or epidermal growth factor receptor RNA species of claim 23 is not required for Group IV while the search required for Group IV such as primers or probes specific for tyrosine kinase RNA species of claim 27 is not required for Group II.

Groups III and IV are distinct and independent inventions in that they are directed to different products. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as primers or probes specific for her-2/neu RNA species of claim 25 is not required for Group IV while the search required for Group IV such as primers or probes specific for tyrosine kinase RNA species of claim 27 is not required for Group III.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species:

(1) epidermal growth factor receptor-directed therapy (claims 5-10)

(2) her-2/neu-directed therapy (claims 11-16)

(3) tyrosine kinase-directed therapy (claims 17-22)

The species are independent or distinct because these therapies are used for different purposes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 1-4.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

April 26, 2006

FRANK LU
PRIMARY EXAMINER